REMARKS

The Office Action of March 10, 2006 presents the examination of claims 1-3. Claim 1 is amended to recite language more in conformity with U.S. practices and to clarify the scope of the range of pH. None of the amendments is narrowing of the scope of the claims. Support for making the range inclusive of the end points is provided by, *e.g.* the data points in the Figures 1 and 2.

The Examiner also indicates that the term "L-lysine salt of ketoprofen" lacks antecedent basis in claim 2. The claim is amended to recite an indefinite article, thus obviating this rejection.

Rejections under 35 USC § 112, second paragraph

The Examiner rejects claims 1-3 under 35 USC § 112, second paragraph, as being indefinite. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner asserts that the term "supporting substances" is unclear. Applicants disagree, noting that the term "supporting substances" is defined in US Patent No. 5,895,789 (WO 97/24114 in the name of the same Assignee), to which reference is made in the present application (page 2, last line). At col. 2, lines 32-35, the '789 patent describes "supporting substances" as those which contribute to the volume and compactness of a lyophilized composition. Therefore, this term is not unclear and the instant rejection should be withdrawn.

Rejection under 35 USC § 102

Claim 1 is rejected under 35 USC § 102(b) as anticipated by Darko et al., US 6,342,530. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner characterizes Darko '530 as describing a pharmaceutical composition having all of the elements of the present claim 1. The Examiner particularly indicates that Example 4 of Darko '530 describes solutions of ibuprofen lysinate substantially free of any

excipient, organic solvent, buffer, acid, base or salt. The Examiner suggests that the example makes reference to the subsequent Table 1 in which samples having a pH from 6.5-8.5 are recorded.

In example 4 of the Darko reference, the pH is adjusted to 7.2 to 7.6. Table 1, to which the example makes reference, indicates that the pH limits on a pooled sample are 6.5 and 8.5.

The Examiner misinterprets the Darko reference. Consideration of the reference as a whole shows that Table 1 merely provides data recorded as the solution for injection is being prepared. See, col. 4, line 66 to col. 5, line 2. This portion of the text makes clear that the solution is mixed, the pH is measured and then, the pH is again adjusted. Darko et al. have no appreciation that an ibuprofen solution for injection should be prepared at pH 8 to 9, and it is not their intent to produce such a solution. Note that col. 5, line 2 describes , "... a target pH of 7.4." Applicants further note that the solutions described by the Examiner as being at pH 6.5 to 8.5 are described as "pooled samples", and therefore, there is no sample "for parenteral administration" that has a pH in the range of 8 to 9. Still further, the range 6.5 to 8.5 is described as "limits" though over what time period and for what purpose are not clearly stated. The Examiner should note, though, that the actual pH is measured as initially 7.5 and that the measured pH is from 7.3 to 7.5 over a period of two years.

Thus, the Darko '530 patent does not disclose any solution of ibuprofen having a pH in the range of 8 to 9. Accordingly, the instant rejection should be withdrawn.

Rejection under 35 USC § 103

Claims 2 and 3 are rejected under 35 USC § 103(a) as being unpatentable over Darko '520 in view of Gentile '789. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants submit that the Examiner fails to establish *prima facie* obviousness of the claimed invention. In particular, the combined references fail to describe or suggest that a solution of an alkylammonium salt of a 2-propionic acid should have a pH in the range of 8 to 9.

The teachings of Darko in this regard have been explained above. Gentile is cited for the preparation of a solution of ketoprofen, as this particular 2-aminopropionic acid is not described or suggested by Darko et al.

Applicants submit that the combination of Gentile with Darko still fails to disclose or suggest to one of ordinary skill in the art that a solution of a 2-propionic acid for injection should have a pH from 8 to 9. Accordingly the Examiner fails to establish *prima facie* obviousness of the present invention.

Furthermore, as well-described by the specification, the present invention unexpectedly provides a solution of a 2-aminopropionic acid that does not cause pain to a subject to which it is administered by parenteral injection. Such an unexpected result provides evidence of unobviousness of the claimed invention.

For all of the reasons explained above, claims 2 and 3 are not obvious in view of the combination of Darko '530 and Gentile '789. Therefore, the instant rejection should be withdrawn.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at

the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

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Respectfully submitted,

By _____

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